Amendments to the Drawings

The attached sheet of drawings includes changes to FIG. 6(C). This sheet, which includes FIGS. 6(A)-(C), replaces the original sheet. In FIG. 6(C), SEQ ID Nos. have been added.

Attachment: Replacement Sheet

Remarks

I. Status of the Claims

Claim 24 is added.

Claims 1, 2, 5, 7, 8, 9, 11, 12, 16, 17, 18, 19 and 22 are amended.

Claims 20-21 are withdrawn reserving the right to file them in a continuing application.

Claims 1-19 and 22-24 are being prosecuted.

II. Alexandrov et al. Does Not Teach All Claim Amendments, Therefore Does Not Anticipate

Claims 1-6, 8-19 and 22-23 were rejected as anticipated by Alexandrov et al. (EP 1033405 A2, published June 9, 2000) "taken with the evidence of Zhu et al." According to the examiner (page 16) SEQ ID NO: 67644 = SEQ ID NO: 2 and SEQ ID NO: 67645 is identical to SEQ ID NO: 1.

Rejections under 35 U.S.C. §102(b) require **all** claim elements to be in the publication cited for support.

The examiner admits that

> Alexandrov et al. do not explicitly disclose increased stress (e.g. cold) tolerance property of their transgenic plants or seeds derived thereof.

Office Action, page 17

but relies on **inherency** and the speculation that if Alexandrov et al. over-expressed SEQ ID NO: 6745 in the plants he disclosed, they would show stress tolerance. Speaking of hindsight! The Alexandrov publication is **344 pages long**, and presents over **70,000 sequences** that are fragments of *Arabidopsis* DNA. **The sequence listing is about 50,000 pages long.** One of skill in the art would only be directed to the application by searching for SEQ ID NO: 1.

In this voluminous publication, every conceivable aspect of plant molecular biology is considered, but finding the pending claim elements is analogous to picking very small needles out of a gigantic haystack. The sections would not have been considered by those interested in plant

stress tolerance without hindsight from the pending application. No one would zero in on SEQ ID NOs: 67644 and 67645 without knowledge of SEQ ID NO: 1 of the present application.

On page 17 of the Office Action, the examiner uses Zhu to fill in the omissions of Alexandrov. The examiner cites Zhu for showing cold tolerance due to overexpression of a sequence identical to SEQ ID NO: 1 in pending claims. However, the citations provided do not support overexpression of a sequence identifier posed to SEQ ID NO: 1 and indeed "overexpression" is not part of all the claims. The Abstract on page 9966 cited by the examiner reports that plants with the *Arabidopsis hos10-1* mutant "are extremely sensitive" to stress such as cold and salt (FIGs. 3 and 4 show *hos10-1* mutant plants are "defective in cold acclimation" and "hypersensitive to NaCl." Page 9969, FIGSs. 5 and 6 show "Water loss and ABA biosynthesis defects in *hos10-1* plants." **Also, the matching of *hos10-1* to a DNA fragment to At1g35515, was retracted. There was a retraction of this publication on July 9, 2010.** The Zhu retraction, July 2010 was that AT1g35515 was **not** responsible for the cold sensitive phenotype of the HOS10 mutant. Altered expression was not as reduced as reported According to the retraction, the locus responsible for the HOS10 phenotype reported in ecotype C24 remains unknown. (C24 was the source of the *hos10-1* mutant).

Because Zhu was redacted, those of skill in the art would not accept its teachings, and regardless it did not teach **any** claim elements missing in Alexandov, there is no anticipation.

Anticipation by inherent disclosure is appropriate only when the reference discloses prior art that **must necessarily include the unstated limitation**. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 1000 (Fed. Cir. 2006) (*emphasis provided*).

When anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown the undisclosed information was **known to be present in the subject matter of the reference**. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). Inherency **cannot be based on the knowledge of the inventor**; facts asserted to be inherent in the prior art must be shown by evidence from the prior art. *In re Debizak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). "If the [prior art] limitation is inherently disclosed... it must be necessarily present and a person of

ordinary skill in the art would recognize its presence." *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (*emphasis provided*).

Inherency, however, may not be established by **probabilities or possibilities**. *In re Robertson*, 169 F.3d 743, 745 (Fed Cir. 1999). The mere fact that a certain thing may result from a given set of circumstances is not sufficient. *Id.* An inherent limitation is one that is necessarily present; invalidation based on inherency is not established by "probabilities or possibilities." *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999).

The examiner has not satisfied any of these requirements so please withdraw this rejection.

III. A Prima Facie Case of Obviousness is Not Established

Claim 7 was rejected as obvious over Alexandrov et al.

All the examiner's cites on pp. 16-19 of the Office Action to Alexandrov are just repeats of basic recombinant technology. The publication includes more than **70,000** sequences (fragments of *Arabidopsis* DNA) including sequences Nos.: 67,644 and 67,645 said to match pending SEQ ID NO: 1. However the examiner admits

> Alexandrov et al. do not teach transforming the transgenic plant overexpressing SEQ ID NO: 67645 with an another nucleic acid encoding a different transcription factor.

but concludes without proof, that Alexandrov makes claim 7 obvious because

> It would have been obvious and within the scope of an ordinary skill in the art to have transformed stress tolerant transgenic plant overexpressing HOS10 polypeptide of SEQ ID NO: 67645 with an additional recombinant polynucleotide encoding a different and unrelated transcription factor of Alexandrov et al. ...

Office Action, page 20

A determination of obviousness requires that "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *KSR International Co. v. Teleflex, Inc.*, -- U.S. --, 127 S.Ct. 1727, 1734, 82 U.S.P.Q.2d 1385 (2007) *quoting Graham v. John Deer Co.*,

383 U.S. 1, 17 (1966). In making a determination of obviousness by looking at the teachings of multiple patents, one should consider

> the effects of demands known to the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. **To facilitate review, this analysis should be made explicit.**

KSR, 127 S.Ct. at 1740-41 (*emphasis added*). "[A] patent composed of several elements is not proved obvious merely by demonstrating the each of its elements was, independently, known in the prior art." *Id.* at 1741. In fact, all the claimed elements are provided by the examiner, not Alexandrov.

IV. Corrections to the Specification Have Been Made; SEQ IDs are Added to FIG 6

In the Office Action, pages 2-4, the examiner requested edits to the specification, specifically to add SEQ ID NOs: to FIG. 6. The amendments have been made.

V. Rejections Under 35 U.S.C. §112 Should Not Be Maintained

Claims 1-4, 6-7, 11 and 22-23 were said only to be enabled for transforming a plant with DNA as set forth in SEQ ID NO: 1.

Claims 1-7 and 22-23 were rejected under 35 U.S.C. §112, 2nd par. Claims 1 and 22 are amended so that the last step in the method matches the preamble. These amendments have been made.

Claims 8, 12, 16-19 have format amendments - parentheses are removed from around (SEQ ID NO: 1).

Claims are enabled for 90% identity with the amino acid sequence SEQ ID NO: 1.

Support for breadth of claim scope beyond SEQ ID NO: 1 in *Arabidopsis thaliana* to improve cold stress resistance, and enablement is at least in the following locations in the specification:

Paragraph	Comment
00009, 00013	90% identical to SEQ ID NO: 1
00010, 00021	stress may be cold osmotic, draught or abcisic acid (ABA)
00011, 00012	plant is monocot or dicot
00019	salt resistance
00021	model plant = *Arabidopsis thaliana*
00025	"plant" includes as broad as amenable to transformation
00028	"'sequence identity' or "identity" in the context of two nucleic acid or polypeptide sequences" – defined so those of skill could determine if 90% identity or more
FIG. 1, 00030	HOS10 negatively controls RD29A::LUC expression in response to low temperature, ABA, or osmotic stress
00040	*hos10-1* mutant plants display enhanced sensitivity to cold, salinity, ABA, HOS10 increases resistance
00043	petunia - petal specific promoters (many other promoters disclosed)
00051 00052, 00053, 00054, 00055	general promoters, pathways, transgenic plants, vectors for transformation, monocots, dicots
00056	conservation of signaling pathways in monocots and dicots
FIG. 6C	structural similarity of HOS10 homologs
00060-00065	transformation methods, monocots and dicots

Those of skill would know how to readily compare a molecule of theirs to SEQ ID NO: 1 in the present application, to see if it had at least 90% identity with SEQ ID NO: 1, thus falling within present claim scope see [00028]. Several types of stress were tested, so that term should not be limited.

Paragraphs [00051] - [00056] and FIG. 6C support extension of claim scope beyond the specific HOS10 SEQ ID NO: 1 and beyond a pathway in *Arabidopsis* to include monocots and dicots. Support for "at least 90% identical to SEQ ID NO: 1", an amino acid sequence, is also found in [00028] in which there is an explanation of why conservative amino acid substitutions, well known to those of skill in the art, can be included in a homolog of SEQ ID NO: 1 and, if function is the same, will still fall within the claim scope.

> The examiner, therefore, **must have a reasonable basis to challenge the adequacy of the written description.** The examiner has the initial burden of presenting by a preponderance of evidence **why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention** defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. MPEP 2163.04. (*emphasis added*).

The Federal Circuit in *In re Curtis* stated that written descriptive support fails "when ... the evidence indicates ordinary artisans could not predict the operability in the invention ... ". *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). In addition, Courts have found adequate written descriptive support based on a representative species, for example when "corresponding written description [can] lead one having ordinary skill in the art to that class of compounds". *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979). Functional recitation of known compounds in the specification "may be sufficient as to that description", because the Court found that the functional limitation would suggest to a person skilled in the art that invention includes a broader use. *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973).

For example, a recent Federal Circuit case reiterates the controlling law that known structures or sequences need not be disclosed in a specification.

> Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. ..... Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk

> to the specification. Accordingly, we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), **satisfaction of the written description requirement does not require either the recitation ...of such genes and sequences**. *Falko-Gunter Falkner v. Inglis,* 448 F.3d 1357, 1363 (Fed. Cir. 2006). (*emphasis added*).

Although the exact words of the amendment are not in the specification, an invention claimed need not be described *ipsis verbis* in the specification in order to satisfy the disclosure requirements. *Ex parte Eggleston* (B.P.A.I. 2005). The MPEP states:

> If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, **even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met**. *See, e.g., Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient"). MPEP 2163, 8th Ed. Rev. 6 (2008). (*emphasis added*).

This logic can be extended to reason that close matches are within the scope of the claims - 90% includes molecules with conservative and other substitutions but that have claimed function.

All the other discussion is not consistent with legal requirements to provide a reasonable range around a claimed sequence.

No statute or case law requires the kind of details the examiner wants:

> Thus, from the guidance in the specification, it would appear that the vast majority of the amino acids in SEQ ID NO: 1 could be changed with any other amino acid.
>
> The instant specification fails to provide guidance for which amino acids of SEQ ID NO: 1 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain the functional activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still

produce a functional protein that functions as a stress tolerant protein.

Office Action, pages 7-8

Undue experimentation as defined in the Wands factors is not required. There is no dispute that SEQ ID NO: 1 is disclosed. Review of the well known conservative amino acid substitutions as a way to create sequences that have at least 90% of the same amino acids as in SEQ ID NO: 1, is in par [00028] of the specification. Those of skill in the art are familiar with other ways to make molecules 90% identical to SEQ ID NO: 1, e.g., truncating sequences and testing for function.

Direction and guidance is available to those of skill. Methods to transform plants with a molecule at least 90% identical to SEQ ID NO: 1 are well known and also described in the specification [00060-00065]. Routine assays to determine if the substituted sequences with at least 90% identity are functional as claimed are also described.

Working examples are provided (e.g., FIGs. 1-7, Examples 1-2) and extrapolation to sequences with 90% identity to SEQ ID NO: 1 is within the knowledge of those of skill, now that the present disclosure directs them to a way to improve plants' response to stresses, using SEQ ID NO: 1 or its equivalents (at least 90% identity).

Claims are not overly broad but in fairness, protect the inventors from infringers that would benefit from the inventive concepts by modifying SEQ ID NO: 1 yet achieve the claimed results, but not literally infringe.

Predictability of results from the well known model, *Arabidopsis* (par [00021]), to monocots and *dicots*, is explained in [00056].

On pages 5-13 of the Office Action, the examiner admits that all the basic steps needed to practice the inventions are described in the specification. The only reason for rejection is the "90% identity" to SEQ ID NO: 1.

There is no need for those of skill to test the function of each and every permentation of amino acid substitutions in SEQ ID NO: 1 as the examiner implies. Guided by well known

methods revealed in [00028], and using disclosed and other known assays, tests within the scope of the claims do not require under experimentation.

90% identity of SEQ ID NO: 1 means that about 70 or more amino acids of a new sequence must be the same. There are not a "myriad of nucleic acids" to screen (Office Action page 9).

Written description is also satisfied by the numerous citations to the specification pointed out in this response showing possession of the claimed invention. Case law on page 11 of the Office Action is not dispositive because a representative species is described (SEQ ID NO: 1) and substitute members of the genus can be written on paper, made and tested for function without undue experimentation.

VI. Conclusion and Summary

No fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (3220-112306).

Respectfully submitted,

Alice O. Martin

Date: March 25, 2011

Alice O. Martin, Reg. No. 35,601
One of the Attorneys for Applicant(s)
BARNES & THORNBURG LLP
P.O. Box 2786
Chicago, Illinois 60690-2786
Phone: 312-357-1313
Facsimile: 312-759-5646
Customer No.: 23644